K062198

DEC 19 2006

14. 510(k) Summary

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of CFR 807.92.

Summary Date: July 10, 2006

Submitter's Information:
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Trade Name: Pre-gelled Disposable Surface Electrodes; Sunspots Pre-gelled Surface Electrodes

Common Name: Pre-gelled Surface Electrodes

Classification Name: Surface Electrode

Classification: Number: 882.1320 Surface Electrode

Product Codes: GXZ

Predicate Devices:
Manufacturer: Nicolet Biomedical
Trade Name: Pre-gelled Surface Electrodes
FDA number: K971914

Manufacturer: Medicotest, Inc.
Trade Name: Surface Electrodes
FDA number: K931030

Manufacturer: Tyco Health Kendall (Graphic Controls)
Trade Name: Medi-Trace 133 ECG Pellet Electrodes
FDA number: K821137

Description: Electrodes are the interface medium between neurodiagnostic or neuromonitoring equipment and the patient. Electrodes are used in electro-diagnostic clinical studies or during intraoperative monitoring for electroencephalography (EEG), electromyography (EMG) or evoked potentials recording and electrical stimulation.

The electrodes used to detect electro-physiological signals or provide electrical stimulation cutaneously. The electrodes are non-

sterile and are designed to be disposable, for single use only.

Pre-gelled Surface Electrodes are noninvasive as they are placed cutaneously or in contact with the skin or muscle surface and are used under the supervision of a licensed physician.

Axon Systems' Pre-gelled Surface Electrodes (PGSE) are supplied with leads or with snap connector.

The leaded electrodes are comprised of a laminated, flexible structure composed of polyester fabric or polyethylene foam and use conductive carbon coated with Ag/AgCl and activated carbon mesh material and conductive hydrogel on one side as the coupling medium to the skin. No other adhesive is used. The active conductor is electrically connected to flexible, copper or carbon fiber lead wire and an industry standard DIN 42802 "touch proof" safety connector on the other end. The safety connector is connected to the recording input or electrical stimulator output of the neurodiagnostic or neuromonitoring equipment.

The snap connector electrode is comprised of a polyethylene foam substrate with medical grade adhesive and uses Ag/AgCl pellet(s) as the conductive element. The active surface of the pellet is coated with conductive hydrogel to form the coupling medium to the skin. The pellet is attached to a male snap which is used to connect the electrode directly to the recording amplifier.

Intended Use: Axon Systems' Pre-gelled Surface Electrodes are intended for use with electrodiagnostic or neurological monitoring equipment for the recording of electrophysiological activity and for peripheral nerve electrical stimulation. The electrodes are non-sterile and for single patient use only.

Technological Comparison: Technologically, the Pre-gelled Surface Electrodes are similar to the predicate devices. The exceptions are in physical dimensions only. No new technology or basic materials are used in these designs.

The Pre-gelled Surface Electrodes were tested functionally using accepted laboratory test procedures.

Conclusions: Based on the technical information provided and the safety and effectiveness criteria of the design and development process, we claim the Pre-gelled Surface Electrodes to be safe, effective and substantially equivalent to the predicate device(s) noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Howard Bailin
VP, Chief Operating Officer
Axon Systems, Inc.
400-2200 Oser Ave.
Hauppauge, NY 11788

DEC 19 2006

Re: K062198
Trade/Device Name: Pre-gelled Surface Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: November 7, 2006
Received: November 9, 2006

Dear Mr. Bailin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K062198

Device Name **Pre-gelled surface electrodes**

Indications for Use

Axon Systems' Pre-gelled Surface Electrodes are intended for use with electrodiagnostic or neurological monitoring equipment for the recording of electrophysiological activity and for peripheral nerve electrical stimulation. The electrodes are non-sterile and for single patient use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062198